



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

CTEP Branch and Support Contracts Forms and Surveys (National Cancer Institute)

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Michael Montello, Pharm.D., Shanda Finnigan, MPH, RN, CCRC or Jacquelyn Goldberg, JD, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, 9609 Medical Center Drive, Rockville, MD 20850 or call non-toll-free number (240-276-6080) or E-mail your request, including your address to: ctsucontact@westat.com.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the Federal Register on February 21, 2018, page 7483 (83 FR 7483) and allowed 60 days for public comment. No public comments were received. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: CTEP Branch and Support Contracts Forms and Surveys, 0925-0753 Expiration Date 06/30/2020, REVISION, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) and the Division of Cancer Prevention (DCP) fund an extensive national program of cancer research, sponsoring clinical trials in cancer prevention, symptom management and treatment for qualified clinical investigators. As part of this effort, CTEP implements programs to register clinical site investigators and clinical site staff, and to oversee the conduct of research at the clinical sites. CTEP and DCP also oversee two support programs, the NCI Central Institutional Review Board (CIRB) and the Cancer Trial Support Unit (CTSU). The combined systems and processes for initiating and managing clinical trials is termed the Clinical Oncology Research Enterprise (CORE) and represents an integrated set of information systems and processes which support investigator registration, trial oversight, patient enrollment, and clinical data collection. The information collected is required to ensure compliance with applicable federal regulations governing the conduct of human subjects research (45 CFR 46 and 21 CFR 50), and when CTEP acts as the Investigational New Drug (IND) holder, FDA regulations pertaining to the sponsor of clinical trials and the selection of qualified investigators under 21 CFR 312.53). Information is also collected through surveys to assess satisfaction, provide feedback to guide improvements with processes and technology, and assess health professional's interests in clinical trials.

To increase efficiencies, reduce administrative burden and cost, CTEP has requested consolidation of their current OMB submission. Consolidation is justified because although the various branches and contracts are responsible for distinct services, the processes that support the NCI and participating clinical sites efforts are intertwined. This revision of the previous submission includes changes to the NCI CIRB and CTSU form collections and integrates the Clinical Trials Monitoring Branch (CTMB) and Pharmaceutical Management Branch (PMB) form collections related to site audit and clinical investigator and key clinical site staff registration.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 112,798.

Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
CTSU IRB/Regulatory Approval Transmittal Form (Attachment A01)	Health Care Practitioner	2444	12	2/60	978
CTSU IRB Certification Form (Attachment A02)	Health Care Practitioner	2444	12	10/60	4888
Withdrawal from Protocol Participation Form (Attachment A03)	Health Care Practitioner	279	1	10/60	47
Site Addition Form (Attachment A04)	Health Care Practitioner	80	12	10/60	160
CTSU Roster Update Form (Attachment A05)	Health Care Practitioner	600	1	5/60	50
CTSU Request for Clinical Brochure (Attachment A06)	Health Care Practitioner	360	1	10/60	60
CTSU Supply Request Form (Attachment A07)	Health Care Practitioner	90	12	10/60	180

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Site Initiated Data Update Form (Attachment A08)	Health Care Practitioner	2	12	10/60	4
Data Clarification Form (Attachment A09)	Health Care Practitioner	150	24	10/60	600
RTOG 0834 CTSU Data Transmittal Form (Attachment A10)	Health Care Practitioner	12	76	10/60	152
CTSU Generic Data Transmittal Form (Attachment A12)	Health Care Practitioner	5	12	10/60	10
CTSU Patient Enrollment Transmittal Form (Attachment A15)	Health Care Practitioner	12	12	10/60	24
CTSU Transfer Form (Attachment A16)	Health Care Practitioner	360	2	10/60	120
CTSU System Access Request Form (Attachment A17)	Health Care Practitioner	180	1	20/60	60
CTSU OPEN Rave Request Form (Attachment A18)	Health Care Practitioner	30	21	10/60	105
CTSU LPO Form Creation (Attachment A19)	Health Care Practitioner	5	2	120/60	20
CTSU Site Form Creation and PDF (Attachment A20)	Health Care Practitioner	400	10	30/60	2000
CTSU PDF Signature Form (Attachment A21)	Health Care Practitioner	400	10	10/60	667
NCI CIRB AA & DOR between the NCI CIRB and Signatory Institution (Attachment B01)	Participants	50	1	15/60	13

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
NCI CIRB Signatory Enrollment Form (Attachment B02)	Participants	50	1	15/60	13
CIRB Board Member Application (Attachment B03)	Board Member	100	1	30/60	50
CIRB Member COI Screening Worksheet (Attachment B08)	Board Members	100	1	15/60	25
CIRB COI Screening for CIRB meetings (Attachment B09)	Board Members	72	1	15/60	18
CIRB IR Application (Attachment B10)	Health Care Practitioner	80	1	60/60	80
CIRB IR Application for Exempt Studies (Attachment B11)	Health Care Practitioner	4	1	30/60	2
CIRB Amendment Review Application (Attachment B12)	Health Care Practitioner	400	1	15/60	100
CIRB Ancillary Studies Application (Attachment B13)	Health Care Practitioner	1	1	60/60	1
CIRB Continuing Review Application (Attachment B14)	Health Care Practitioner	400	1	15/60	100
Adult IR of Cooperative Group Protocol (Attachment B15)	Board Members	65	1	180/60	195
Pediatric IR of Cooperative Group Protocol (Attachment B16)	Board Members	15	1	180/60	45
NCI Adult/Pediatric Continuing Review of Cooperative Group Protocol (Attachment B17)	Board Members	275	1	60/60	275

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Adult Amendment of Cooperative Group Protocol (Attachment B19)	Board Members	40	1	120/60	80
Pediatric Amendment of Cooperative Group Protocol (Attachment B20)	Board Members	25	1	120/60	50
Pharmacist's Review of a Cooperative Group Study (Attachment B21)	Board Members	50	1	120/60	100
Adult Expedited Amendment Review (Attachment B23)	Board Members	348	1	30/60	174
Pediatric Expedited Amendment Review (Attachment B24)	Board Members	140	1	30/60	70
Adult Expedited Continuing Review (Attachment B25)	Board Members	140	1	30/60	70
Pediatric Expedited Continuing Review (Attachment B26)	Board Members	36	1	30/60	18
Adult Cooperative Group Response to CIRB Review (Attachment B27)	Health Care Practitioner	30	1	60/60	30
Pediatric Cooperative Group Response to CIRB Review (Attachment B28)	Health Care Practitioner	5	1	60/60	5
Adult Expedited Study Chair Response to Required Modifications (Attachment B29)	Board Members	40	1	30/60	20
Reviewer Worksheet- Determination of UP or SCN (Attachment B31)	Board Members	400	1	10/60	67

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Reviewer Worksheet -CIRB Statistical Reviewer Form (Attachment B32)	Board Members	100	1	15/60	25
CIRB Application for Translated Documents (Attachment B33)	Health Care Practitioner	100	1	30/60	50
Reviewer Worksheet of Translated Documents (Attachment B34)	Board Members	100	1	15/60	25
Reviewer Worksheet of Recruitment Material (Attachment B35)	Board Members	20	1	15/60	5
Reviewer Worksheet Expedited Study Closure Review (Attachment B36)	Board Members	20	1	15/60	5
Reviewer Worksheet of Expedited IR (Attachment B38)	Board Members	5	1	30/60	3
Annual Signatory Institution Worksheet About Local Context (Attachment B40)	Health Care Practitioner	400	1	40/60	267
Annual Principal Investigator Worksheet About Local Context (Attachment B41)	Health Care Practitioner	1800	1	20/60	600
Study-Specific Worksheet About Local Context (Attachment B42)	Health Care Practitioner	4800	1	20/60	1600
Study Closure or Transfer of Study Review Responsibility (Attachment B43)	Health Care Practitioner	1680	1	20/60	560
Unanticipated Problem or Serious or Continuing Noncompliance	Health Care Practitioner	360	1	20/60	120

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Reporting Form (Attachment B44)					
Change of Signatory Institution PI Form (Attachment B45)	Health Care Practitioner	120	1	20/60	40
Request Waiver of Assent Form (Attachment B46)		60	1	20/60	20
CTSU OPEN Survey (Attachment C03)	Health Care Practitioner	60	1	15/60	15
CIRB Customer Satisfaction Survey (Attachment C04)	Participants	600	1	15/60	150
Follow-up Survey (Communication Audit) (Attachment C05)	Participants/ Board Members	300	1	15/60	75
CIRB Board Member Annual Assessment Survey (Attachment C07)	Board Members	60	1	15/60	15
PIO Customer Satisfaction Survey (Attachment C08)	Health Care Practitioner	60	1	5/60	5
Concept Clinical Trial Survey (Attachment C09)	Health Care Practitioner	500	1	5/60	42
Prospective Clinical Trial Survey (Attachment C10)	Health Care Practitioner	1000	1	1/60	17
Low Accrual Clinical Trial Survey (Attachment C11)	Health Care Practitioner	1000	1	1/60	17
Audit Scheduling Form (Attachment D01)	Group/CTMS Users	152	5	21/60	266
Preliminary Audit Findings Form (Attachment D02)	Auditor	152	5	10/60	127

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Audit Maintenance Form (Attachment D03)	Group/CTMS Users	152	5	9/60	114
Final Audit Finding Report Form (Attachment D04)	Group/CTMS Users	75	11	1098/60	15098
Follow-up Form (Attachment D05)	Group/CTMS Users	75	7	27/60	236
Roster Maintenance Form (Attachment D06)	CTMS Users	5	1	18/60	2
Final Report and CAPA Request Form (Attachment D07)	CTMS Users	12	9	1800/60	3240
NCI/DCTD/CTEP FDA Form 1572 for Annual Submission (Attachment E01)	Physician	23,000	1	15/60	5750
NCI/DCTD/CTE Biosketch (Attachment E02)	Physician; Health Care Practitioner	33,000	1	120/60	66,000
NCI/DCTD/CTEP Financial Disclosure Form (Attachment E03)	Physician; Health Care Practitioner	33,000	1	5/60	2750
NCI/DCTD/CTEP Agent Shipment Form (ASF) (Attachment E04)	Physician	23,000	1	10/60	3833
Totals		136,487	207,989		112,838

Dated: April 12, 2018.

Karla Bailey,

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National Cancer Institute, National Institutes of Health.

